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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,362	01/19/2001	Solomon S. Steiner	1951300.00047	8907

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
11/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/766,362	STEINER ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7,8,10-12,14,16-18,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7,8,10-12,14,16-18,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response, Amendment, Applicant's Arguments/Remarks, the Declaration under 37 C.F.R. §1.132 and the NPL Article (Respiratory Drug Delivery, VIII, 2002), all filed 08/10/09 is acknowledged.

Applicant has overcome the following rejection by virtue of the amendment to the claims: (1) The 35 U.S.C. §112, second paragraph rejection of claim 1 (for the term "a drug") has been withdrawn.

Claims 1, 3-5, 7, 8, 10-12, 14, 16-18, 20 and 21 are pending in this action. Claims 1 and 12 have been amended. Claims 2, 6, 9, 13, 15 and 19 were previously cancelled. Claims 1, 3-5, 7, 8, 10-12, 14, 16-18, 20 and 21 remain rejected.

* * * * *

Information Disclosure Statement

The information disclosure statement (NPL Article - Respiratory Drug Delivery, VIII, 2002) submitted 21 January 2009 and 10 August 2009 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "preferentially" in claim 1 is a relative term which renders the claim indefinite. The term "preferentially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the term cannot be reasonably ascertained. It is suggested that this term either be positively recited or deleted.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-5, 7, 8, 10-12, 14, 16-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steiner *et al.* (hereinafter "Steiner") (U.S. Pat. No. 5,503,852) in view of Illum (US. Pat. No. 5,690,954).

Steiner *et al.* ('852) teach drug delivery systems based on the formation of diketopiperazine microparticles and microencapsulation of drugs by derivatives of diketopiperazine, wherein the microparticles are formed in the presence of the drug to be delivered and are between 0.1 to 10 microns in diameter and whereby the microparticles are used for diagnostic applications for imaging of the nasal tract (see reference col. 4, lines 30-55); (col. 10, lines 25-49); (col. 13, lines 13-24) and Abstract.

According to Steiner, biologically active agents having therapeutic, prophylactic or diagnostic activities can be delivered and include active agents, such as hormones, vasoactive agents, anesthetics or sedatives, steroids, decongestants, antivirals, antisense, antigens, antibodies and the like (col. 10, lines 25-49).

Steiner *et al*. teach a system based upon diketopiperazine or one of its substitution derivatives, including *diketomorpholines and diketodioxanes*. The diketopiperazine synthetic intermediates are preferably formed by cyclodimerization to form diketopiperazine derivatives at elevated temperatures under dehydrating conditions, functionalized on the side chains, and then precipitated with drug to be incorporated into microparticles (see abstract; col. 4, lines 49-67; col. 7, lines 8-11).

The protective material, the diketopiperazines, are not biologically active and do not alter the pharmacologic properties of the therapeutic agents (col. 11, lines 1-3).

The instant invention is drawn to a composition for the nasal administration of a drug in dry powder form for administration to the nasal region, whereby the dry powder comprises microparticles having a particle size of 10 to 20 microns and comprising drug and a diketopiperazine. There is no patentable distinction observed between the instant invention and the prior art since the prior art teaches drug delivery systems based on the formation of diketopiperazine microparticles and microencapsulation of drugs by derivatives of diketopiperazine, wherein the microparticles are between 0.1 to 10 microns in diameter and are used for nasal applications. Steiner explicitly teaches that their microparticles can be between 0.1 and 10 microns. Thus, the '10 micron' size microparticles disclosed by Steiner overlaps with the "10 microns" claimed herein by Applicant and hence the "10 microns" of Steiner satisfies the

claim limitation requirement of "10 to 20 microns". The 10 microns taught by the prior art is an overlapping particle size that falls within the range of "10 to 20 microns" instantly claimed and thus reads on the instant particle size limitations. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). In this case, Applicants have not established that their claimed range provides for unexpected results over the ranges disclosed by the art. Moreover, Applicant themselves assert that "about 10 microns" would be a suitable micron size in order for the particles to remain in the nasal cavity.

Furthermore, Applicants have not demonstrated that the "10 micron" size range claimed is a critical lower limit. This is evidenced by Applicant's own specification. For instance, formulations I and II on pages 13 and 14 demonstrate particles with micron sizes that are less than 10 microns. More specifically, formulation I on p. 13 demonstrates that 10% of particles had a particle size of only *3.15* microns. Similarly, Formulation II on page 14 demonstrates that 10% of particles had a particle size of only *2.99* microns. Therefore, this clearly establishes that the 'between 10 microns' claimed by Applicants is not a critical lower maximum particle size limitation. The determination of a suitable or effective particle size is within the level of one of ordinary skill in the art, based on routine experimentation. Regarding the instant method of administering a dry powder comprising microparticles, one of ordinary skill in the art would have been motivated to nasally administer the microparticles of Steiner that comprise a drug and diketopiperazine and further optimize, if necessary, the particle size or size range for the intended application (i.e., nasal applications). One would be motivated to do this with a

reasonable expectation of success of obtaining an enhanced drug delivery system that effectively (nasally) administers the microparticles in the (nasal) cavity for maximum treatment. Regarding the limitation of "wherein the composition does not pass into the pulmonary system", recited in instant claims 1, 7 and 14, it is the position of the Examiner that the 10-micron sized microparticles of Steiner, which overlap with the "about 10 microns" instantly claimed would be retained in the mucosal cavity for sufficient drug delivery and would not pass into the pulmonary system and thus, would be suitable for their intended purpose. Thus, this teaching of the "10 micron-sized" microparticles of Steiner meets this limitation requirement. Absent a showing of evidence to the contrary, Steiner's microparticles would also be retained in the nasal cavity as Steiner teaches that their microparticles are suitable for nasal administration.

Regarding Applicant's limitation of "wherein more than 50% of the particles have a size greater than about 10 microns", it is the position of the Examiner that Applicant presents no data establishing that the 50% particle size limitation would be an improved result over the presence of the smaller micron-sized particles of the art. Moreover, Steiner teaches microparticles that include 10 microns in diameter and thus recognizes an overlapping particle size with that of the instant claims.

As stated above, biologically active agents disclosed include those having therapeutic, prophylactic or diagnostic activities can be delivered and include active agents, such as hormones, vasoactive agents, anesthetics or sedatives, steroids, decongestants, antivirals, antisense, antigens, antibodies and the like (col. 10, lines 25-49).

With respect to the limitation "suitable for administration of a drug" in claim 1, it is noted that "drug" has not been defined in the specification. Thus, the term has been given its broadest reasonable interpretation.

Steiner does not teach an antihistamine (*i.e.*, chlorpheniramine) and a device for nasal administration (i.e., nasal insufflator).

Illum ('954) teaches a drug delivery system for *nasal administration* of an active drug in *dry powder form* wherein the drug delivery system comprises microsphere particles formed of active drugs that include *antihistamines*, vasoconstrictors, anti-inflammatory agents and anesthetics whereby the composition is administered in the form of a dry powder having a particle size of from about 10 microns to about 100 microns (see reference column 5, line 14 through col. 6, line 53); (col. 9, lines 24-61). (The range of about 10 microns to about 100 microns taught by Illum encompasses the range of "10 to 20 microns" claimed by Applicant).

Suitable active drugs disclosed are anti-inflammatory agents, vasoconstrictors, anesthetics (analgesics) and antihistaminic agents. Antihistaminic agents are diphenhydramine hydrochloride, *chlorpheniramine maleate* and clemastine. The microspheres are administered via the nasal route using a *nasal insufflator device.* Examples of these are already employed for commercial powder systems intended for nasal application (*e.g.*, Fisons Lomudal System); (col. 8, line 44 through col. 9, line 60). The teaching of a (nasal insufflator) device meets the limitations of a device as recited in instant claims 7-12.

Illum teaches that the drug to be administered to a mucosal surface such as the *nose*, eye, etc., can be administered as a powder and can also be administered in the form of a colloidal particle comprising a microsphere system (col. 5, line 14-26).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the antihistamines (*i.e.*, chlorpheniramine) as taught by Illum within the microparticulate formulations of Steiner. One would be motivated to do so with a reasonable expectation of success because Illum teaches a nasally administered drug delivery system and device (nasal insufflator) comprising antihistamines, such as those claimed (chlorpheniramine), which are effective medicaments useful for treating allergic conditions, administered via nasal administration and provided in a dry powder form for sufficient drug delivery to the nasal mucosa. The expected result would be an improved microparticulate drug delivery system for nasal administration, useful for treating allergy symptoms.

Hence, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the explicit teachings of Steiner in combination with Illum.

* * * * *

Response to Arguments

Applicant's arguments filed 08/10/09 have been fully considered and were found partially persuasive.

- **Claim Rejections - 35 USC § 112:**

Applicant argued, "Applicants have amended claim 2 to replace the term "drug" with "antihistamine".

This argument was persuasive by virtue of the amendment to claim 1. Accordingly, the 35 U.S.C. §112, second paragraph rejection of claim 1 (for the term "a drug") has been withdrawn.

Applicant also argued, "Claim 2 had been previously cancelled, therefore applicants are unsure which claim the Office is referring to and have not been able to address this part of the rejection."

The "claim 2" 112, second paragraph rejection contained a typographical error and was intended to read as "claim 1" for the term "preferentially" as this term is only recited in claim 1 of the instant claim set. Claim 1 is the only instance where the term "preferentially" occurs. This term is a relative term which has not been clearly defined. This rejection has been maintained herein.

- **Rejection under 35 U.S.C. §103(a) of claims 1, 2, 4, 5, 7, 9, 11, 12, 14, 15, 17 and 18 over Steiner et al. (US Pat. No. 5,503,852) and Rejection under 35 U.S.C. §103(a) of claims 3, 8, 10, 16, 20 and 21 over Steiner et al. (USPN 5,503,852) in view of Illum (USPN 5,690,954):**

Applicant argued, "Steiner discloses particles between 0.1 to 10 microns in diameter. Steiner does not disclose microparticles wherein more than 50% of the particles have a size greater than about 10 microns. Steiner does not teach that the majority of the particles are greater than 10 microns in size and does not suggest particles retained in the nasal cavity."

This argument has been considered but was not found persuasive. Regarding Applicant's limitation of "wherein more than 50% of the particles have a size greater than about 10 microns",

while Steiner does not teach the percentage range of particles that are greater than about 10 microns, Steiner, nonetheless, does teach microparticles that are 10 microns in diameter and thus recognizes an overlapping particle size with that of the instant claims, which requires between about 10 and about 20 microns. Furthermore, it is the position of the Examiner that the 10-micron sized microparticles of Steiner, which overlap with the "between about 10 microns" instantly claimed would be retained in the mucosal cavity for sufficient drug delivery and would not pass into the pulmonary system and thus, would be suitable for their intended purpose. Thus, this teaching of the "10 micron-sized" microparticles of Steiner meets this limitation requirement. Absent a showing of evidence to the contrary, Steiner's microparticles would also be retained in the nasal cavity as Steiner teaches that their microparticles are suitable for nasal administration. In addition, Applicant themselves assert that "about 10 microns" would be a suitable micron size in order for the particles to remain in the nasal cavity. See page 2, 2nd paragraph of the instant specification. Since Steiner teaches "10 micron-sized" microparticles, these particles of Steiner would also be retained in the nasal cavity, thus meeting Applicant's limitation requirement. Furthermore, Applicants have not demonstrated that the "10 micron" size range claimed is a critical lower limit. This is evidenced by Applicant's own specification. For instance, formulations I and II on pages 13 and 14 demonstrate particles with micron sizes that are less than 10 microns. More specifically, formulation I on p. 13 demonstrates that 10% of particles had a particle size of only *3.15* microns. Similarly, Formulation II on page 14 demonstrates that 10% of particles had a particle size of only *2.99* microns. Therefore, this clearly establishes that the 'between 10 microns' claimed by Applicants is not a critical lower particle size limitation

The Declaration under 37 CFR 1.132 of Dr. Marshall Grant filed 08/10/09 has been fully considered. The Declaration is insufficient to overcome the rejection of claims 1, 3-5, 7, 8, 10-12, 14, 16-18, 20 and 21 based upon the 35 U.S.C. 103(a) rejection as set forth in the last Office action. It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. In this regard, Applicant argues "that the microparticles for nasal administration of the instant invention are physically different from the microparticles of Steiner and that Steiner does not teach a method for making microparticles for nasal delivery or microparticles useful for nasal delivery. Applicant further states that the microparticles of Steiner are co-precipitated microparticles and are prepared by a different process than the coated microparticles of the instant invention and thus have different physical and physiochemical characteristics (Declaration, paragraphs 11-18)."

These arguments have been considered, but were not rendered persuasive since Applicants are not claiming a method of making microparticles, but rather are claiming a composition or product in addition to the method of administering and a device, of which the prior art clearly demonstrates such a composition, method and device. The instant claims are not drawn to a process for making coated microparticles, thus, Applicant's arguments do not establish the scope of claims being presented. Even assuming *arguendo*, that the instant claims were drawn to product-by-process claims, the Examiner points out that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is

based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Hence, the argument that "Steiner's microparticles are prepared by a different process and would have different physical and physiochemical characteristics" was not persuasive. Steiner sufficiently teaches a composition and drug delivery systems based on diketopiperazine microparticles and microencapsulation of drugs by derivatives of diketopiperazine, wherein the microparticles are between 0.1 to 10 microns in diameter. . In response to applicant's argument that "Steiner does not teach microparticles useful for nasal delivery", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is noted that the limitation of "for nasal administration" in instant claims 1 and 7 denotes a future-intended use of the composition and thus, does not accord patentable weight to the instant claims. In any event, the 10 micron-sized particles of Steiner (which overlap with the "10 microns" claimed by Applicant) would be retained in the nasal cavity and would not pass into the pulmonary system. In this regard, Steiner further discloses that their particles are used for diagnostic applications for imaging of the nasal tract.

Regarding the Wilson et al. article - Respiratory Drug Delivery, VIII, 2002, Applicant stated "the Wilson reference establishes the 10 micron critical lower limit of the microparticles

size for optimal nasal administration without deposition of the microparticles in the taste centers or in the deep lung."

The Wilson et al. reference has been reviewed and considered but does not distinguish the explicit teachings of Steiner over the limitations of the instant claims. As delineated above, Steiner vividly recognizes and teaches microparticles having a size as claimed (i.e., 10 microns) and thus, the microparticles of Steiner, which are of the same size as the instant microparticles, would also be retained in the nasal cavity, 'without deposition in the taste centers or in the deep lung', absent a showing of evidence to the contrary.

Applicant further states, "Example 3 supports the assertion that the claimed microparticles are retained in the nasal cavity and do not pass into the pulmonary system. Steiner teaches away from using larger microparticles and the particles of Steiner are not suitable for administration to, and retention in, the nasal cavity without passing into the pulmonary system."

This argument was not convincing. It would have been obvious to one of ordinary skill in the art that the microparticles of Steiner would be retained in the nasal cavity, based on Steiners' teaching of particles having a size of 10 microns (Steiner teaches a range of from 0.1 to 10 microns - col. 4, lines 30-55, col. 10, lines 25-49). Since Steiners' range overlaps with that of the instant claims, the particles of Steiner would be retained in the nasal cavity and would not pass into the pulmonary system. The particles of Steiner would further not cause a bitter taste, since they would be retained in the nasal cavity. Hence, the particles of Steiner would be suitable for their intended purpose (i.e., administration to the nasal cavity). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of

obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). The "10 micron-sized" particles of Steiner satisfy the "between about 10 microns" claimed by Applicant. One of ordinary skill in the art would have been motivated to nasally administer Steiner's microparticles, which are comprised of drug and diketopiperazine, and, if necessary, would also optimize the particles size range for the intended or particular application.

Regarding Illum, Applicant argued, "Illum does not remedy the deficiencies of Steiner. Illum states that the microspheres should be of a size between 10 and 100 microns. While there is overlap in the range of the claimed microparticles and the microspheres of Illum, Illum does not teach or suggest microparticles between about 10 microns and about 20 microns in diameter wherein more than 50% of the particles have a size greater than about 10 microns."

These arguments were not rendered convincing. Regarding Applicant's limitation of "wherein more than 50% of the particles have a size greater than about 10 microns", it is the position of the Examiner that Applicants have not established any unexpected results over the teachings of the prior art. The primary reference of Steiner teaches microparticles that include 10 microns in diameter and thus recognizes an overlapping particle size with that of the instant claims. The 10 micron-sized particles of Steiner overlap with the "10 microns" claimed herein by Applicant and thus would be retained in the nasal cavity and would not pass into the pulmonary system. Steiner further discloses that their particles are used for diagnostic applications for imaging of the nasal tract. With regards to the secondary reference of Illum, Illum was relied upon for the teaching of employing antihistamines in a drug delivery system for nasal administration of an active drug in dry powder form. The drug delivery system comprises

microsphere particles formed of active drugs that include antihistamines, whereby the composition is administered in the form of a dry powder having a particle size of from about 10 microns to about 100 microns. See column 5, line 14 - col. 6, line 53; col. 9, lines 24-61. This particle size range clearly encompasses, overlaps and meets the instant particle size of "between about 10 microns and about 20 microns". ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809(CCPA 1969). Illum also teaches suitable antihistaminic agents that include chlorpheniramine maleate as claimed herein. The microspheres are administered via the nasal route using a nasal insufflator device. See col. 8, line 44 through col. 9, line 60. In addition, Illum also identifies sources for nasal insufflators employed for commercial powder systems intended for nasal application (col. 9, lines 53-61). Illum additionally explains the advantages of nasal delivery (col. 1, line 62 - col. 2, line 3). Thus, the secondary reference sufficiently fills the deficiency of the primary reference based on the former's teaching of delivering antihistamines in dry powder form to the nasal cavity, using a nasal insufflator device. Hence, one of ordinary skill in the art would have been motivated to combine the teachings of Steiner and Illum with a reasonable expectation of success, as both references are directed to drug delivery systems useful for administration to the nasal mucosa.

The rejections of record have been maintained.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

* * * * *

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

November 23, 2009